



**PENNSYLVANIA
MEDICAL MARIJUANA
PROGRAM**

Evaluation Committee Training
March 23, 2017



Agenda


- ➡ • Medical Marijuana Program
- Regulations
- Evaluation Process
- Goals and Responsibilities



Medical Marijuana Program

Vision

The Pennsylvania Department of Health's vision is to have a high quality, efficient and compliant medical marijuana program for commonwealth residents with serious medical conditions as defined by Act 16.




Medical Marijuana Program

Mission

When fully implemented, the Medical Marijuana Program will provide access to medical marijuana for patients with a serious medical condition through a safe and effective method of delivery that balances patient need for access to the latest treatments with patient care and safety.

The Medical Marijuana Program will also promote high quality research into the efficacy of medical marijuana in treating a patient's serious medical condition.




Medical Marijuana Program

Guiding Principles

The Pennsylvania Department of Health will strive to develop and maintain a Medical Marijuana Program that is viewed as:



- medically-focused program benefitting patients
- effective communication
- consistent, competent and efficient
- leading, innovative, research-driven program
- transparent



Medical Marijuana Program

What is medical marijuana?

- Pills, oil, topical forms such as patches or ointments
- A form medically appropriate to vaporize
- Tinctures and liquids

Medical Marijuana Program

What is a serious medical condition?

- Amyotrophic Lateral Sclerosis
- Autism
- Cancer
- Crohn's Disease
- Damage to the nervous tissue of the spinal cord with objective neurological indication of intractable spasticity
- Epilepsy
- Glaucoma
- HIV/AIDS
- Huntington's Disease
- Intractable spasticity
- Inflammatory bowel disease
- Intractable seizures
- Multiple Sclerosis
- Neuropathies
- Parkinson's Disease
- Post-traumatic Stress Disorder
- Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or ineffective
- Sickle Cell Anemia



Medical Marijuana Program

Who will be able to obtain medical marijuana?

Patients who are residents of the commonwealth who have a serious medical condition that have been certified by a practitioner may obtain medical marijuana.

A patient may name a caregiver and the caregiver may obtain the medical marijuana for the patient.



Pennsylvania General Assembly

2016 Act 16

MEDICAL MARIJUANA ACT - ENACTMENT
Act of Apr. 17, 2016, P.L. 66, No. 16

Establishing a medical marijuana program providing for patient and caregiver certification and for medical marijuana organizations; establishing temporary duties on the Department of Health providing for a tax on medical marijuana organizations; establishing the Medical Marijuana Program; establishing the Medical Marijuana Policy Board; establishing a medical marijuana research program; imposing duties on the Department of Corrections, the Department of Public Safety and the Department of Human Services and providing for various clinical research centers and for penalties and enforcement.

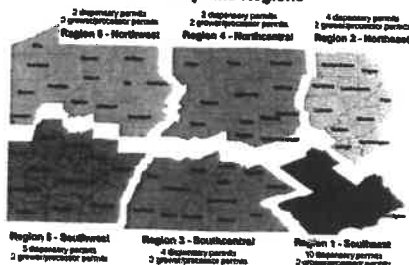
TITLE: OF CONTENTS
Chapter 1. Preliminary Provisions
Section 101. Short title.
Section 102. Declaration of policy.
Section 103. Definitions.

From plant to patient



Medical Marijuana Regions

Pennsylvania Department of Health Medical Marijuana Regions



Applicants must...



- Applications must be mailed by March 20th deadline
- Responses are on electronic media
- Application fees and permit fees enclosed



Where do we come in?

- The objective of the evaluation committee is to provide a thorough, unbiased assessment of the submitted applications
- Phase 1 permits must be decided by June 30, 2017
- The Medical Marijuana Act and the temporary regulations are to be followed when evaluating applications



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Temporary Regulations

- 28 Pa. Code:
 - § 1141 – General Provisions
 - § 1151 – Grower/Processors
 - § 1161 – Dispensaries

CHAPTER 1141. GENERAL PROVISIONS
§ 1141.01. Definitions.
 The following words and terms, when used in this part, have the following meanings, unless the context clearly indicates otherwise:

Act—The Medical Marijuana Act (85 P.S. §§ 10231.101–10231.2110).

Adverse event—An injury resulting from the use of medical marijuana dispensed at a dispensary. An injury includes physical harm, mental harm or loss of function.

Adverse loss—A loss, discrepancy in inventory, diversion or theft of seeds, immature medical marijuana plants, medical marijuana plants, medical marijuana, funds or other property of a medical marijuana organization.

Advertising—The publication, dissemination, solicitation or stimulation, for a fee, that is visual, oral, written or electronic to induce directly or indirectly an individual to patronize a particular dispensary or to purchase particular medical marijuana.

Temporary Regulations

- The Medical Marijuana Act (MMA), 35 P.S. §§ 10231.101-10231.2110 (Act 16 of 2016)
Signed into law April 17, 2016
Effective May 17, 2016
- The Act provides that the Department of Health's authority to adopt temporary regulations expires two years after the effective date of the Act
- First temporary regulations were released by the department on June, 2016



Temporary Regulation Areas

- Safe Harbor Letters and Minor § 1131
- Medical Marijuana – General Provisions § 1141
- Growers/Processors § 1151
- Dispensaries § 1161
- Laboratories § 1171
- Practitioners § 1181
- Patients and Caregivers § TBD
- Advisory Board § TBD
- Chapter 20 – Research § TBD



Definitions

- **Marijuana**
The plant, of genus *Cannabis sativa* L., within the family Cannabaceae, including any part of the plant genus *Cannabis*, within the family Cannabaceae and the immature plant or seeds of the plant genus *Cannabis*, within the family Cannabaceae
The term does not include industrial hemp
- **Medical marijuana**
Marijuana for certified medical use under the Act
- **Medical marijuana product**
The final form and dosage of medical marijuana that is grown, processed, produced, sealed, labeled and tested by a grower/processor and sold to a dispensary



Definitions

- **Medical marijuana plant**
 - A plant which is greater than 12 vertical inches in height from where the base of the stalk emerges from the growth medium to the tallest point of the plant, or greater than 12 horizontal inches in width from the end of one branch to the end of another branch
- **Immature medical marijuana plant**
 - A rootless, nonflowering part of a medical marijuana plant that is no longer than 12 inches and no wider than 12 inches produced from a cutting, clipping or seedling and that is in a growing container that is no larger than 2 inches wide and 2 inches tall that is sealed on the sides and bottom



Review of Permits § 1141.33

- **Act 16, Section 603(a.1) Factors to consider when approving permits:**

The applicant will maintain effective control of and prevent diversion of medical marijuana

The applicant will comply with all applicable laws of this Commonwealth

The applicant is ready, willing and able to properly carry on the activity for which a permit is sought

The applicant possesses the ability to obtain in an expeditious manner sufficient land, buildings and equipment to properly grow, process or dispense medical marijuana

It is in the public interest to grant the permit

The applicant, including the financial backer or principal, is of good moral character and has the financial fitness necessary to operate

The applicant is able to implement and maintain security, tracking, recordkeeping and surveillance systems relating to the acquisition, possession, growth, manufacture, sale, delivery, transportation, distribution or the dispensing of medical marijuana as required by the department

The applicant satisfies any other conditions as determined by the department



Thought You Were Done?

- **1141.24 (b): The Department will consider the following factors about each region in its determination to grant or deny a permit:**
 - Regional population
 - The number of patients suffering from a serious medical condition
 - The types of serious medical conditions in the region
 - Access to public transportation
 - The health care needs of rural and urban areas
 - Areas with recognized need for economic development



Other Provisions § 1141

- **Initial Permit Application § 1141.29**
 - Locations and Site Design
 - Business Structure and History
 - Plan of Operation
- **Diversity Goals § 1141.32**
 - Each medical marijuana organization shall include in its permit application a diversity plan that establishes a goal of equal opportunity and access in employment and contracting by the medical marijuana organization



Growers/Processors § 1151

- **Growers/Processors Facilities § 1151.23**
 - A grower/processor may only grow, store, harvest or process medical marijuana in an indoor, enclosed, secure facility as approved by the Department
- **Security and Surveillance § 1151.26**
 - A grower/processor shall have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse loss
- **Requirements for Growing § 1151.27**
 - A grower/processor shall use only pesticides, fungicides or herbicides that are approved by the Department of Agriculture for use on medical marijuana plants and listed in Appendix A (relating to acceptable pesticide active ingredients for use). Pesticides § 1151.43



Growers/Processors § 1151

- **Storage Requirements § 1151.31**
 - A grower/processor shall have separate locked limited access areas for storage of seeds, immature medical marijuana plants, medical marijuana plants and medical marijuana held for disposal
- **Sanitation and Safety § 1151.33**
 - A grower/processor shall maintain its facility in a sanitary condition to limit the potential for contamination or adulteration of the medical marijuana grown and processed in the facility
- **Packaging and Labeling § 1151.34**
 - A grower/processor shall package and label at its facility each form of medical marijuana prepared for sale



Growers/Processors § 1151

- **Transportation § 1151.35 -37**
 - A grower/processor may transport and deliver medical marijuana to a medical marijuana organization in this Commonwealth
 - A grower/processor shall generate a printed or electronic transport manifest that accompanies every transport vehicle
 - A grower/processor may transport seeds, immature medical marijuana plants and medical marijuana plants within this Commonwealth for the growing and processing of medical marijuana
- **Disposal of Medical Marijuana § 1151.40**
 - Medical marijuana waste generated by a grower/processor shall be stored, collected and transported in accordance with 25 Pa. Code Chapter 285 (relating to storage, collection and transportation of municipal waste), provided the medical marijuana waste is not hazardous



Dispensaries § 1161

- **Generally § 1161.22**
 - A dispensary may not employ an individual at its facility who is under 18 years of age
 - May employ licensed medical professionals: physicians, pharmacists, physician assistants, certified registered nurse practitioners. § 1161.25
- **Dispensing Medical marijuana § 1161.23**
 - A dispensary may only dispense medical marijuana to a patient or caregiver who presents a valid identification card to an employee at the facility
 - Dispensing medical marijuana is determined by the practitioner recommendation in a patient certification



Dispensaries § 1161

- **Dispensary Facilities § 1161.26**
 - A dispensary may only dispense medical marijuana to a patient or caregiver in an indoor, enclosed, secure facility
 - A dispensary may not be located:
 - Within 1,000 feet of the property line of a public, private or parochial school, or a day-care center
 - At the same site used for growing and processing medical marijuana in the same office space as a practitioner or other physician
- **Items and Services Provided § 1161.27**
 - A dispensary may sell, offer for sale or provide at its facility, with the prior written approval of the Department, instruments, devices and services related to the use of medical marijuana



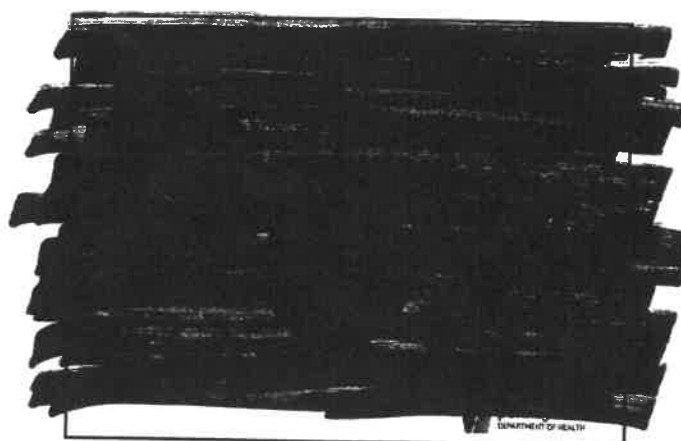
Dispensaries § 1161

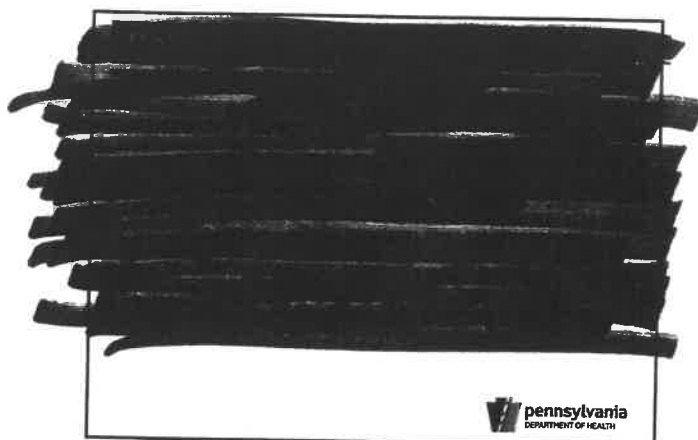
- **Labels and Safety § 1161.28**
 - Medical marijuana products must only be identified by the name of the grower/processor, the name of the dispensary, the form and species of medical marijuana, the percentage of THC and CBD contained in the medical marijuana product
- **Security and Surveillance § 1161.31**
 - A dispensary shall have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse loss
- **Transportation § 1161.35 - 36**
 - A dispensary may transport and deliver medical marijuana to a medical marijuana organization in this Commonwealth.
 - A dispensary shall generate a printed or electronic transport manifest that accompanies every transport vehicle



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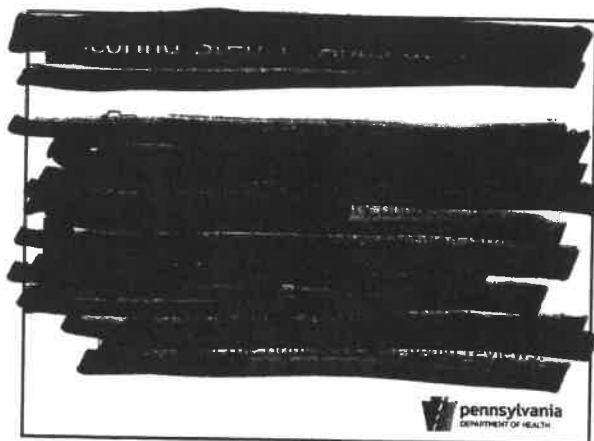
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Standardized scoring

- SMEs will provide guidance
- Committee members use scoring worksheet
- Score against the guidance

If the total number of points = Then scores are as follows	25	50	75	100
Exceeds Expectations	21-25	41-50	66-75	81-100
Better Than Average	16-20	31-40	46-65	61-80
Meets Expectations	11-15	21-30	31-45	41-60
Below Expectations	6-10	11-20	16-30	21-40
Not Acceptable	0-5	0-10	0-15	0-20

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Scoring Step 2: Read & Prepare

- Read, comprehend and assess applications **before** the committee meets to discuss them
- Use worksheets to record score recommendations, questions and notes
- Assess each application on its own merit - **DO NOT** compare to other applications
- Most important: **Come to the scoring meeting prepared**
- No time is available during a meeting to read/evaluate applications



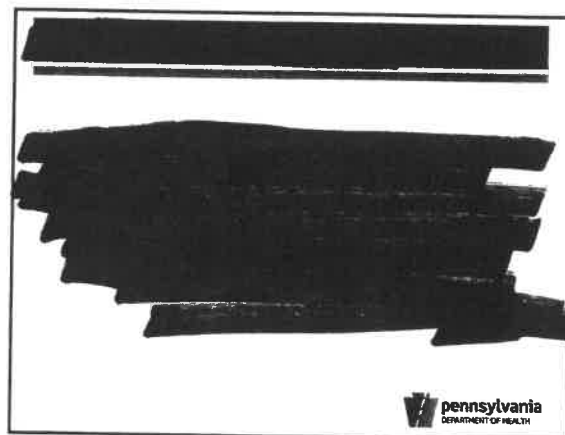
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Scoring Step 3: Meet & Score

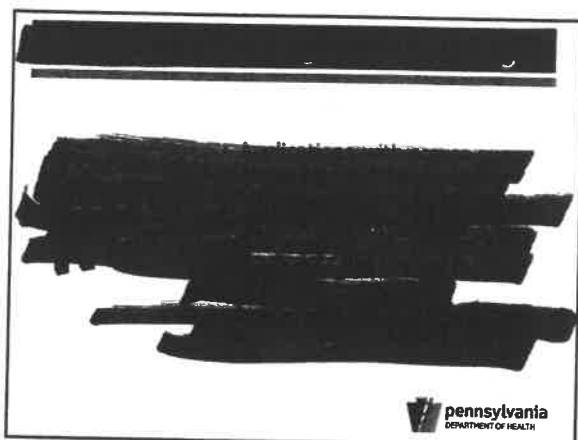


- Agenda (sent in advance) will list applications to be considered
- Again, **come prepared!**
- Facilitation to ensure fair and complete review of each application
- Present observations; recommend scores
- Input + process = output

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Tentative Schedule

- **Short-Term**
 - Today: Introduction to applicant documents; SME assignments
 - Friday: SME scoring guidance
 - Next week: Applications delivered
- **Long-term**
 - Meet 3 times each week
 - Agenda announced in advance
 - Process wraps up by end of June

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* Pre-decisional document.
Dates subject to change.

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Objective

- Identify the best applicants, using the criteria specified in the Act:
 - The applicant will maintain effective control of and prevent diversion of medical marijuana
 - The applicant will comply with all applicable laws of this Commonwealth
 - The applicant is ready, willing and able to properly carry on the activity for which a permit is sought
 - The applicant possesses the ability to obtain in an expeditious manner sufficient land, buildings and equipment to properly grow, process or dispense medical marijuana



Objective

- Identify the best applicants, using the criteria specified in the Act (continued):
 - It is in the public interest to grant the permit
 - The applicant, including the financial backer or principal, is of good moral character and has the financial fitness necessary to operate
 - The applicant is able to implement and maintain security, tracking, recordkeeping and surveillance systems relating to the acquisition, possession, growth, manufacture, sale, delivery, transportation, distribution or the dispensing of medical marijuana as required by the Department



Objective

- The following factors about each medical marijuana region also may be considered:
 - Regional population
 - The number of patients suffering from a serious medical condition
 - The types of serious medical conditions in the region
 - Access to public transportation
 - The health care needs of rural and urban areas
 - Areas with recognized need for economic development



Team "Code of Conduct"

- You must comply with the confidentiality agreement
- No conflicts of interest
- Give each applicant fair and equal treatment
- All determinations are based only on the application – DO NOT consult outside resources
- No contact, direct or indirect, with any applicant
- Commit to the process: read all applications, follow directives, attend all meetings



Conflict of Interest

- Definition: Use by a public official or public employee of the authority of his office or employment or any confidential information received through his holding public office or employment for the private pecuniary benefit of himself, a member of his immediate family or a business with which he or a member of his immediate family is associated.
- The term does not include an action having a de minimis economic impact or which affects to the same degree a class consisting of the general public or a subclass consisting of an industry, occupation or other group which includes the public official or public employee, a member of his immediate family or a business with which he or a member of his immediate family is associated.



De Minimis Economic Impact

- Definition: An economic consequence which has an insignificant effect.



Special Considerations

- DO NOT discuss the applications or scoring with anyone, including other committee members, outside of the Evaluation Committee meetings
- You must commit to attend ALL Evaluation Committee meetings
- Always ask the committee chair if you are not sure about something

